

U.S. DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
**FILED**

JUN 6 2005

CLERK, U.S. DISTRICT COURT

By RC  
Deputy

Rule 56(a) of the Federal Rules of Civil Procedure does not allow a party to seek determination

of an element of a claim, without attempting to dispose of the claim in its entirety. The “all or a part thereof” language in the rule authorizes the granting of an action only on some claims in a multiple claim action, but not when the motion does not dispose of any claim in its entirety. Likewise Rule 56(d) operates only to salvage issues when the Court has expended judicial effort in denying a proper summary judgment motion, and cannot be used to evade the restrictions in Rule 56(a).

***Summary Judgment for Plaintiff Is Not Appropriate on the Warnings Claims.*** Plaintiff cannot establish entitlement to summary judgment on either her negligent warning claim or her strict liability marketing defect claim. While Plaintiff sets forth many alleged “facts” relating to the warnings issue, she only makes two legal arguments in support of her motion, neither of which entitle her to summary judgment. First, Plaintiff argues that in foreign countries, Wyeth’s OTC Advil products contain a SJS/TEN warning directly to the consumer, and because the Children’s Advil OTC product in the United States does not contain such a warning, it is inadequate as a matter of law. Plaintiff cites no authority in support of this argument. Moreover, Plaintiff’s evidence, to which Wyeth has objected, does not establish that in foreign countries, Wyeth directly warns consumers of SJS/TEN. Even if Plaintiff did establish such a fact (and Plaintiff did not), foreign labeling is irrelevant to whether a U.S. drug is adequately labeled. Plaintiff’s own expert admits that there are different regulations between non-U.S. countries and the U.S., and Wyeth’s evidence, as well as the authority cited by Wyeth demonstrates that requirements for drug labeling in foreign countries has no bearing at all on whether a drug is properly labeled in the United States. *See* Wyeth’s Brief in Support, Section II(C).

Again citing no law, Plaintiff secondly argues that the FDA’s April 2005 announcement that it has “determined that the labeling for all non-prescription NSAIDs should be updated to

warn of the potential for skin reactions” somehow establishes that the Children’s Advil OTC label — which Plaintiff claims should have specifically warned of SJS/TEN — is inadequate as a matter of law. In an attempt to bolster her position, Plaintiff references a Citizen’s Petition she and others filed, asking the FDA to require ibuprofen manufacturers to specifically warn of SJS/TEN, but the very evidence Plaintiff relies on shows that the FDA has merely taken the Citizen’s Petition “under review.” The FDA’s recent announcement, which merely reflects the FDA’s intent as to future labeling and relates to warnings of “skin reactions,” not SJS/TEN specifically, does not establish that the OTC Children’s Advil label is inadequate as a matter of law. *See* Wyeth’s Brief in Support, Section II(D). Wyeth further presents evidence to the Court from its FDA expert that the label for its OTC Children’s Advil contained adequate and appropriate warnings of the product’s dangers, such that the Children’s Advil at issue in this case was not unreasonably dangerous as marketed. *See* Wyeth’s Brief in Support, Section II(E). Plaintiff has failed to demonstrate the absence of a genuine issue of material fact as to either of her warnings claims, and her motion for summary judgment should be denied.

***Plaintiff Is Not Entitled to Partial Summary Judgment on the Issue of Causation.***

***General Causation.*** Plaintiff cannot establish her entitlement to summary judgment on general causation because at the end of the day she has only a single epidemiological study to support her claim – the SCAR study. Neither the CAMP study nor the BUFS study support general causation. The final report of the CAMP study showed a relative risk of 1.52, which is not statistically significant, and the BUFS study only addressed EM (not SJS, which is at issue here) and reported an “absolute risk” as opposed to a relative risk, which is what is required under the case law. *See* Wyeth’s Brief in Support, Section III(B). The published literature relied on by Plaintiff (consisting of case reports, anecdotal evidence, and adverse drug event reports)

likewise cannot support general causation because such evidence lacks credibility and scientific reliability. *Id.* Plaintiffs' claim that all the experts agree (including Wyeth's experts) that a "causal relationship exists between and SJS/TEN) is simply not true. Dr. Robert Stern has testified that there is a very low and comparable risk of SJS/TEN with acetaminophen and ibuprofen, and that the risk is less than one in a million for persons that have used the drug for one week. Similarly, Dr. Roujeau has testified that while there is an "association" between ibuprofen and SJS/TEN, he does not believe the evidence shows even a "strong" association between ibuprofen and SJS/TEN and certainly is not sufficient to show a casual relationship. Likewise, Dr. Shulman has testified to the "association," but clarified this is very different from a causal relationship. *Id.*

***Specific Causation.*** Plaintiff's specific causation argument focuses almost exclusively on the Lymphocyte Toxicity Assay (LTA) test that was administered at the behest of Plaintiff's counsel on March 7, 2005, and not provided to Wyeth until after the expert designation deadline expired. Plaintiff purports to name the physicians who administered the test as "fact witnesses," when interpretation of such a test would clearly call for expert testimony. Plaintiffs experts have also attempted to rely on the test as evidence of causation, despite the fact that such expert testimony is beyond the scope of timely expert designations and outside the opinions provided in their detailed expert reports. The LTA should not be considered as summary judgment proof since it violates the Court's expert designation deadline. *See* Section III(C). Moreover, the summary judgment record does not even contain competent proof of the LTA test results, and Wyeth asserts numerous, valid objections to this evidence *Id.*; *see* Objections to Plaintiffs' Summary Judgment Evidence, *infra*, at Plaintiff's Attachment 24. Even if the test could be considered, the test does not conclusively establish specific causation here in the face of expert

testimony from Drs. Roujeau and Stern that the usefulness of the test in clinical practice is very limited, and that no data or scientific, peer-reviewed literature supports the LTA test as a good predictive value for ibuprofen. *Id.*

Finally, Plaintiffs' reliance on the Bradford-Hill criteria to support summary judgment on specific causation is misplaced. That criteria cannot prove or disprove causality, according to its own author. Even applying three of the nine factors that Plaintiff chose to address, shows Plaintiff is not entitled to summary judgment. Because Plaintiff has only one epidemiological study and the recent EuroSCAR study does not confirm the association with ibuprofen and SJS/TEN, the "strength of association" and "consistency of results" factors cannot support summary judgment. Likewise, the facts relating to the "temporal relationship" factor support summary judgment on causation for Wyeth, not for Plaintiff. *See id.*; *see also* Wyeth's Motion for Summary Judgment and Brief in Support.

### **OBJECTIONS TO PLAINTIFFS' SUMMARY JUDGMENT EVIDENCE**

#### **General Objection:**

- Wyeth objects to Plaintiffs' failure to comply with LCivR 56.5(c) which provides that a party whose motion is accompanied by an appendix must include in its brief citations to *each page of the appendix that supports each assertion that the party makes concerning the summary judgment evidence*. Specifically, footnote numbers 31, 44, 48, 58, 63, 66, 67, 70, 71, 73, 74, 76, 82 through 89, 93, and 100 in Plaintiffs' Motion **do not** cite the pages of the appendix supporting the assertion, and many of the references are to lengthy expert affidavits and/or reports.

**Plaintiffs' Attachment 1:** <http://www.fda.gov/bbs/topics/news/2005/NEW01171.html>

- This document is hearsay, unauthenticated and unverified.

**Plaintiffs' Attachment 12:** Memo of Judith Jones to Arthritis Advisory Comm.

- This document is both hearsay and irrelevant.

**Plaintiffs' Attachment 13:** Cooper Deposition Exhibit 7 (Arthritis Advisory Comm. information); Exhibit 10 – Statement on the Release of Ibuprofen as an OTC Medicine

- Exhibit 7: The documents are hearsay and irrelevant (*see* objection to Att. 12).
- Exhibit 10: The document is hearsay; it is not a learned treatise.

**Plaintiffs' Attachment 14:** Letter from FDA CDER to American Home Products

- This is not an FDA document but actually a letter from American Home Products to the FDA, and thus the document cannot establish what the FDA wanted as that would be hearsay.

**Plaintiffs' Attachment 17:** Defendants' Statement in JSR (3-17-05 draft)

- Statements in a draft pleading that was never filed are hearsay and not admissible.

**Plaintiffs' Attachment 19:** Foreign Labeling

- These documents are objectionable because (1) they are labels for Advil, not Children's Advil, (2) they are warnings that do not go to consumers directly; and (3) they do not reference SJS or TEN.
- The translations of the German and Dutch foreign labels are not properly authenticated by showing that they are accurate translations that done by a competent, qualified translator, and thus the attachment lacks the proper foundation for the admission of a translation.

**Plaintiffs' Attachment 22:** Expert Report of Dr. Julien

- An unsworn expert report is hearsay, and not admissible as summary judgment evidence.

**Plaintiffs' Attachment 23:** 3/13/02 Stern, et al., Final Report to Pharmacia, Inc.

- This report is not sworn and is hearsay. This document is not a learned treatise; the published article qualifies as a learned treatise.

**Plaintiffs' Attachment 24:** BUMC Lab Records

- This evidence violates the expert designation deadline in this Court's scheduling order and the agreement of the parties.
- Plaintiffs have not designated Dr. Rusty Nicar or Dr. Manuela Neuman as expert witnesses or provided expert reports for them despite the fact that any test interpretation would require scientific, technical or other specialized knowledge.
- The BUMC records are not the best evidence of the LTA test and the actual LTA test results are not included in the records.

- Dr. Nicar cannot authenticate a test performed by Dr. Neuman in Canada as he has no personal knowledge of the LTA test results
- The LTA results in the records are based on a hearsay email exchange which constitutes double hearsay since Dr. Neuman is not a Baylor employee, and the hearsay is not excused by the business records exception since the source of the information is an outsider.
- The absence of the LTA test itself makes it impossible to determine whether the test satisfies the requisite *Daubert* standard for reliability.
- The summary judgment record contains no evidence of Dr. Neuman's qualifications and experience with regard to performing and analyzing LTA tests, no evidence about how the actual test in this case was performed and analyzed, no evidence that the LTA test is scientifically reliable for testing toxicity with regard to ibuprofen, and no evidence vouching for the accuracy of the test performed.
- Plaintiffs' experts Tackett and Salisbury cannot rely on the LTA results to reach conclusions about causation in this case because such testimony would exceed the scope of their expert designations/expert reports.

**Plaintiffs' Attachment 26:** Aff. and Report of Tackett

- Dr. Tackett is not a medical doctor or an epidemiologist and is therefore not qualified to render opinions about liability or general or specific causation in this case. He has no experience in diagnosing and treating patients. Furthermore, his opinions are not scientifically reliable. His opinions are based on speculation and on case reports, anecdotal evidence, ADEs, and other information that is not credible or reliable. Many of his assumptions are incorrect or flawed, thus causing his conclusions to be erroneous. Wyeth will be filing a motion to exclude or limit the opinions of Dr. Tackett.

**Plaintiffs' Attachment 27:** Aff. and Report of Dr. Robert Nelson

- Dr. Nelson is not a medical doctor or an epidemiologist and is therefore not qualified to render opinions about liability or general causation in this case. He has no experience in diagnosing and treating patients. Furthermore, his opinions are not scientifically reliable. His opinions are based on speculation and on case reports, anecdotal evidence, ADEs, and other information that is not credible or reliable. Many of his assumptions are incorrect or flawed, thus causing his conclusions to be erroneous. Wyeth will be filing a motion to exclude or limit the opinions of Dr. Nelson.

**Plaintiffs' Attachment 28: Aff. of Dr. Copenhaver**

- Dr. Copenhaver is not qualified to opine on whether ibuprofen caused LaBrea Williams' SJS/TEN because such an opinion is beyond his area of expertise. Dr. Copenhaver is board certified in pediatrics and pediatric pulmonology, but he has only treated two patients with SJS or TEN, and one was treated after the acute phase. (Depo. 50-52). He has never published any articles about SJS or TEN or done research on either. (Depo. 55) He has never diagnosed SJS or TEN in a patient. (Depo. 120). Wyeth will be filing a motion to exclude or limit the opinions of Dr. Copenhaver.

**Plaintiffs' Attachment 29: Aff. and Report of Dr. Cheryl Blume**

- Dr. Blume is not a medical doctor and is therefore not qualified to render opinions about specific causation. Dr. Blume is also not an epidemiologist, and is therefore not qualified to render opinions about general causation in this case, including the CAMP study. Furthermore, her opinions are not scientifically reliable. Her opinions are based on speculation and on other information that is not credible or reliable. Many of her assumptions are incorrect or flawed, thus causing her conclusions to be erroneous. Wyeth will be filing a motion to exclude or limit the opinions of Dr. Blume. Moreover, when discussing foreign labels in her affidavit, Dr. Blume fails to attach any of the supposed European labels she received, in violation of the best evidence rule. Wyeth also objects to Blume's unsworn report that is attached to her affidavit but is not verified by the affidavit.

**Plaintiffs' Attachment 30: Aff. and Report of Dr. Moses Grossman**

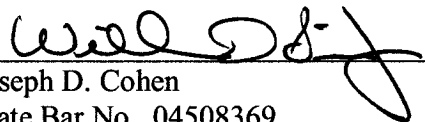
- An unsworn expert report is hearsay, and not admissible as summary judgment evidence. Dr. Grossman does not authenticate or verify his report in his affidavit.
- Many of Dr. Grossman's assumptions are incorrect or flawed, thus causing his conclusions to be erroneous. Dr. Grossman's deposition has not yet been taken. Wyeth reserves the right to file a motion to exclude or limit the opinions of Dr. Grossman.
- Plaintiff designated Dr. Grossman as a purported "rebuttal" witness after her deadline to designate expert witnesses had passed. Given that Plaintiff has the burden of proof in this case, Defendants contend that Plaintiff is not entitled to designate "rebuttal" witnesses. Defendants intend to file a motion to strike Dr. Grossman.



**Plaintiffs' Attachment 31: Report of Dr. Salisbury**

- An unsworn expert report is hearsay, and not admissible as summary judgment evidence.

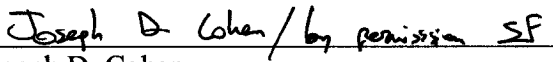
Respectfully submitted,

  
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**ATTORNEYS FOR DEFENDANTS**

**CERTIFICATE OF SERVICE**

This is to certify that a true and correct copy of the foregoing document has been sent to Plaintiff's counsel of record on the 6th day of June, 2005, via hand delivery and Certified mail, Return Receipt Requested.

  
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Joseph D. Cohen